Date : 17 November 2014

# Field Safety Notice

## Urgent Medical Device Correction – 2955842-05212014-002-C

*Labeling Update for da Vinci® Standard, S, Si and Si-e Surgical Systems, Instruments and Accessories*

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| **Introduction and Reason for Field Action** | Dear *da Vinci* Customer,<br><br>The purpose of this Urgent Medical Device Correction is to advise you that Intuitive Surgical is initiating a voluntary correction related to labeling updates to distributed User Manuals, Instructions for Use (IFU), Quick Reference Guides (QRG), collectively referred to herein as "Labeling," and the Natural Rubber Latex (NRL) QRG as well as an Instrument Release Kit (IRK) for use with *da Vinci* Surgical Systems, Instruments and Accessories. The Labeling updates have been implemented to incorporate user feedback.<br><br>This correction does not impact the performance of the *da Vinci* Standard, S or Si Surgical Systems, its instruments or accessories. This correction does not apply to the *da Vinci* Xi Surgical System.<br><br>An Intuitive Surgical Representative will provide an in-service visit to review the labeling changes outlined in Attachment A that could have more significant implications on patient safety. User feedback addresses various product use scenarios, and these scenarios and their potential implications on patient safety are outlined in Attachment B. A detailed list of all labeling changes is provided in Attachment C. No product removal is required, with the exception of the removal of the old Emergency Grip Release Wrench that is being replaced by the Instrument Release Kit (IRK).<br><br>With this Notice you are receving updated Labeling and the IRK.<br><br>**Note: The updated Labeling and IRK supersede any old versions of Labeling and the Emergency Grip Release Wrench. All previous versions of these documents and the Emergency Grip Release Wrench should be discarded.** |
| **Risk to Health** | Intuitive Surgical has received a total of 66 unique adverse event reports associated with use scenarios that were not previously addressed in Labeling for the *da Vinci* Standard, S, Si or Si-e Surgical System, Instruments and Accessories. Attachment B to this Notice summarizes those use scenarious into categories and the potential health consequences associated with each category of Labeling. |
| **Affected Countries and Products** | **Affected Countries:**<br>Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Columbia, Cyprus, Czech Republic, Denmark, Dominican Republic, Egypt, Finland, France, Germany, Great Britain, Greece, Guadeloupe, Hong Kong, India, Indonesia, Iceland, Ireland, Israel, Italy, Luxembourg, Japan, Kuwait, Lebanon, Malaysia, Mexico, Monaco, Netherlands, New Zealand, Norway, Pakistan, Philippines, Panama, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovak Republic, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Taiwan, Turkey, Uruguay, United States of America, Venezuela, and Vietnam.<br><br>**Affected Labeling and IRK:**<br>Please see Attachment D for affected Manuals, IFU's, QRG's and IRK by country and language. |

Date : 17 November 2014

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| **Actions to be taken by the Customer/User** | Please take the following actions:<br>**1.** Ensure all appropriate personnel are fully informed of this Notification. Forward this letter to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform *da Vinci* surgery procedures.<br>**2.** Review labeling changes and related information as outlined in Attachments A, B and C. Use Attachment D to identify the specific labeling that has been updated in your language.<br>**3.** No user manuals or other labeling should be returned. Discard old versions of the User Manuals, IFUs, and QRGs for which you have received updated versions.<br>**4.** No products should be returned. Discard all versions of the Emergency Grip Release Wrench (Part Number 710142). Order additional IRKs from Intuitive Surgical as needed.<br>**5.** Complete and return the attached Acknowledgement Form to acknowledge that you have received the updated Labeling, IRKs, in-service and have discarded all previous versions of Labeling and the Emergency Grip Release Wrench. Please return the completed Acknowledgment Form within two days of the in-service.<br>**6.** Retain a copy of this Notice and your completed Acknowledgement Form for your records. |
| **Action to be taken by Intuitive Surgical** | **1.** Intuitive Surgical representatives will be available by phone to answer questions related to this Urgent Medical Device Correction.<br>**2.** An Intuitive Surgical Representative will perform an in-service relating to the information in Attachment A of this Notice and will be available to answer any questions you may have. |
| **Further Information & Support** | If you need further information or support concerning this Notice, please contact your Intuitive Surgical Representative or Intuitive Surgical Customer Service at the numbers listed below:<br>• North America and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)<br>• Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)<br>• South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)<br>• Europe, Middle East, India, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm) or ics@intusurg.com |

Please be informed that the appropriate Regulatory Authority for your region has been notified of this notification.

Sincerely,

Intuitive Surgical

Date : 17 November 2014

# Field Safety Notice

## Urgent Medical Device Correction – 2955842-05212014-002-C

*Labeling Update for da Vinci® Standard, S and Si Surgical Systems, Instruments and Accessories.*

*Hospital Name*: <mail merge field>
*Address*: <mail merge field>
*City, State, Zip*: <mail merge field>
System Number: <mail merge field>
*NSID:* <mail merge field>
*ATTENTION*: <mail merge field>

By signing this form, I acknowledge that I have received, read and understand the content of this Urgent Medical Device Correction and Attachments. I confirm completion of the following actions:

1. I have ensured all appropriate personnel are fully informed of the contents of this Notice.
2. I have reviewed the labeling changes and related information as outlined in Attachments A, B and C.
3. I have identified the old Emergency Grip Release Wrench (PN 710142) and have replaced it with the Instrument Release Kit (IRK). I confirm that I have discarded the old Emergency Grip Release Wrench.
4. I have received an in-service of the information in Attachment A conducted by an Intuitive Surgical Representative.

**Name (print):** _____

**Signature:** _____

**Hospital Name:** _____

**Phone Number:** _____

**Email:** _____

**Date:** _____

**Position:**

- ☐ **Robotics Coordinator**
- ☐ **Operating Room Director**
- ☐ **Risk Manager**
- ☐ **Recall Coordinator**
- ☐ **Other:** _____

**PLEASE RETURN THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc. WITHIN TWO DAYS OF IN-SERVICE**

**ATTN: REGULATORY COMPLIANCE**

**Subject line for email: Labeling Update**

**U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com**

**Please contact Customer Service if you have additional questions**

- North and South America: 800-876-1310 Option 3 (6 am to 5pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)
- South Korea: 02-3271-3200 (9am to 6pm KSTJ)
- Europe, Middle East, India, Africa and Asia: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or email ics@intusurg.com

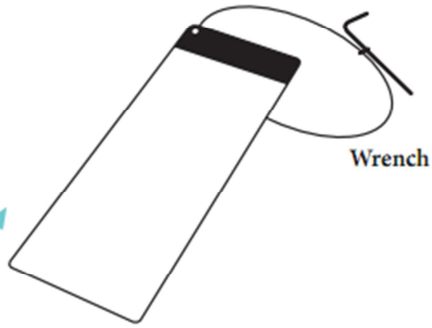
# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment A – *In-Service Checklist*

### Instrument Release Kit In Service Checklist

*da Vinci Standard, da Vinci S, da Vinci Si, da Vinci Si-e*

- ☐ The Instrument Release Kit consists of a wrench and instruction tag. The instruction tag has different instructions on Side 1 and Side 2.
- ☐ Carefully read each step to familiarize yourself with the process of manual grip release. For a complete list of manual grip release warnings and cautions refer to the system user manual.
- ☐ Pressing Emergency Stop ensures the system is properly faulted to successfully perform manual grip release.
- ☐ The direction of wrench rotation is unique for each instrument. Turning the wrong direction may cause unintended instrument motion or damage to the grip release mechanism.




**Side 1**

**8 mm & 5 mm Instruments**
**(See reverse side for Vessel Sealer)**

1. Press **Emergency Stop** on right-side of Surgeon Console.
2. Insert wrench and rotate 1/4 turn.
   - For *Harmonic* Instruments and 8 mm Clip Appliers
   - For other 8 mm, 5 mm, and *Single-Site*® Instruments
3. Clear tissue from grips.
4. Remove wrench, then instrument. **Do not reuse instrument.**

**Troubleshooting**
**Contact dVSTAT**

United States
800-876-1310
International
+800 0821 2020 or
+41 21 821 2020

Instrument Release Kit

*da Vinci Standard, S, Si, Si-e*

**Side 2**

**Vessel Sealer**
**(See reverse side for other instruments)**

1. Press **Emergency Stop** on right-side of Surgeon Console.
2. Do not use wrench.
3. Turn and hold thumbwheel.
4. Clear tissue from grips.
5. Release thumbwheel, and then remove instrument.

**Troubleshooting**
**Contact dVSTAT**

United States
800-876-1310
International
+800 0821 2020 or
+41 21 821 2020

Instrument Release Kit

*da Vinci Standard, S, Si, Si-e*

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment A – *In-Service Checklist*

### Tip Cover Accessory Installation – Before Use

The Tip Cover Accessory is provided in a sterile pouch for a single use. Install the Tip Cover Accessory onto the instrument in the sterile field.

1. Close the scissor blades.

2. Straighten the wrist of the instrument. See Figure 1 below.

3. Grasping the Tip Cover Accessory with the Installation Tool as shown in Figure 1, slide the Tip Cover Accessory onto the distal end of the instrument until it comes to a stop. A twisting motion can be used to ease installation. The distal end of the instrument should be facing away from you during installation.

***Figure 1: Sliding the Tip Cover Accessory onto the instrument***

4. Remove the Installation Tool and retain it to aid in removing the Tip Cover Accessory after use. The Tip Cover Accessory is properly installed when the orange surface is completely covered. See Figure 2.

***Figure 2: Properly installed Tip Cover Accessory in place***

The Tip Cover Accessory is ***not*** properly installed if any part of the orange surface is visible, as shown in Figure 3.

*Figure 3: Tip Cover Accessory not properly installed*

It is also not properly installed if installed beyond the orange surface and over the shaft. This causes a bulge on the shaft and may prevent it fitting through the cannula.

*Figure 4: Tip Cover over-installed*

**WARNING: Failure to install the Tip Cover Accessory properly may result in:**

- **Improper scissor opening**
- **Tip Cover Accessory falling off**
- **Electrical arcs and alternate site burns**

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment B – Risk to Health Appendix

## Attachment C – Identification of Labeling Changes

## Attachment D - Affected Manuals, IFU's, QRG's and IRK by Language and Country

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment B – Risk to Health Appendix

| Use Category | Potential Health Consequence |
|---|---|
| Improper Electrosurgical (ESU) use | **Use of non-compatible ESUs:**<br>Intuitive Surgical has validated a series of 3rd party ESUs for use with the *da Vinci* systems. When the generator is validated, the energy output is characterized so that max settings can be communicated to the user along with guidance on compatible modes. Since many generators use common plug configurations, Intuitive Surgical's EndoWrist instruments can be connected to generators that have not been validated. In this case, there is the scenario of using settings and modes that are not compatible with the system. These scenarios are discussed further below.<br><br>**Use of incorrect cautery modes:**<br>There are ESUs that offer 'auto-fire' settings. In this setting, the generator automatically fires when the grips of the instrument are closed. If the user is unaware that they are operating in this setting, energy will deliver unexpectedly when they grasp tissue with the instrument. This can lead to unintended tissue damage.<br><br>**Exceeding recommend settings:**<br>EndoWrist instruments are rated for a max voltage threshold. If power settings are selected that supply higher voltage than the instruments are rated for, the high voltages could cause insulation break down. This can create arcing from unexpected areas of the wrist, leading to unintended tissue damage. |
| Improper/Unplugged System Connections | **Disconnection/power-down of non-user facing components:**<br>The *da Vinci* system has multiple components that need to be powered and properly connected for the system to be used. The instrument control box (ICB) is a part of the system that sits on the vision cart and controls the vessel sealer and stapler instruments. Like the other components, the ICB needs to be powered and connected in order for the rest of the system to be used but unlike the other components, the main power and connection are not intended for interaction by the users. If the users unintentionally disconnect/power-down the ICB, and do not know how to reconnect, the system will not be available for use. This could result in aborts of da Vinci procedures. |
| Procedure for Converting While Instrument is Grasping Tissue | **Inability to release grips with manual grip release:**<br>The EndoWrist instruments have a hex socket on the top of the instrument input disk and a corresponding hex wrench that can be used in the event that the system faults and the user needs to manually release grasped tissue. However, the system needs to be in a fault state in order for release to work (motors need to be in soft lock). Otherwise, the system motors cannot be over driven by the wrench. If the user does not know to press e-stop if the system is not in a faulted state, they will not be able to move the grips with the wrench to release the tissue. This could result in unintended tissue damage and potential delays in converting a procedure if necessary.<br><br>**Wrong instrument/arm moved during conversion:**<br>Frequently in a case, the patient side assistant is instructed by the surgeon to exchange instruments or move an arm of the system. In the case of a conversion, the patient side assistant would be tasked with clearing the instruments and arms from the surgical field. If the patient side assistant removes or moves the incorrect instrument, it could cause unintended tissue damage. This is especially likely if the instrument mistakenly moved was grasping tissue at the time. |
| Unintended Use of Instruments | **Use of Snap-Fit blades outside of intended use:**<br>The paddle instrument and 15 degree blades were specifically designed for use in dissection and preparation of vessels for arteriotomies. These surgical tasks are precise and delicate. In the scenario where the blades are used for more aggressive tasks (i.e. to transect the uterus for removal) there is a risk of damaging the blade or pulling the blade out of the snap-fit |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment B – Risk to Health Appendix

| Use Category | Potential Health Consequence |
|---|---|
| | instrument. This could result in a sharp fragment falling into the patient. |
| Improper Installation of Tip Accessory | **Incorrect installation of the Tip Cover Accessory:**<br>There are two key potential hazards that may result from incorrectly installing the tip cover. First, there is the potential of the instrument getting stuck in the cannula, since an over-installed tip cover causes the outer diameter of the instrument to be too large to fit down through the cannula. Second, if the tip cover has been over- installed, the tip cover can be pulled off the instrument during instrument removal and dropped in the patient. These scenarios have the potential to cause harm if the difficulty inserting the instrument causes the instrument to stick and then slip forward into tissue, or if the fallen tip cover is not identified and removed. |
| Instrument to Instrument Interactions | **Instrument to instrument collision damages distal tip of instruments:**<br>During a procedure, if the distal end of an instrument being used is repeatedly colliding with another instrument with significant force, both instruments can be damaged and drop fragments into the patient. These fragments have different potential compositions, included ceramic or Ultem pieces from the cautery instruments, pieces of tungsten cable, stainless steel grip tips from a variety of instruments or titanium pieces from the Harmonic instrument. These pieces would have to be identified and retrieved in order to completely mitigate risk to patient.<br><br>**Interoperative cleaning causes tip damage:**<br>During a procedure, tissue accumulates on the tips of all instruments, especially cautery instruments. If a second instrument is used to remove the debris from the instrument, one or both instruments can be damaged in the same way as described above.<br><br>**Instrument to shaft collision causes shaft damage:**<br>Similar to above, if collisions are made between the shaft of two instruments, the shafts can be damaged and particulates can fall in the patient. In the case of the 5mm instruments, this can lead to skiving off a piece of the nylon coating. This piece would have to be identified and retrieved in order to completely mitigate risk to patient.<br><br>**Instrument to Tip Cover collision causes damage:**<br>In the case of instrument collisions with the tip cover, the tip cover can be damaged. If not identified, this could result in arcing through the damaged areas of the tip cover and potential unintended tissue damage. |
| Incorrect Vision Settings | **Low illuminator settings cause a dark image:**<br>The required vision settings are different for each case. The settings can be adjusted to optimize the image based on tissue, working distance, etc. In the case where the vision settings have been adjusted without the surgeon realizing it, the image can be made too dim to complete the necessary surgical tasks. If the settings are not adjusted, it can lead to conversion of the surgery to an alternative surgical approach. |
| Instrument Removal | **Failure to straighten instrument prior to instrument removal:**<br>While instruments are back-drivable and will straighten when pulled out of the cannula, it is more abusive to the instrument to have the instrument straightened by the cannula during removal rather than the surgeon straightening the distal tip prior to removal. If the instrument is not straightened and is extracted quickly and forcefully, this can lead to impact loads on the distal components of the instruments. Some of the instruments have potential to be damaged in this scenario and could result in pieces falling in the patient, especially the ceramic sleeves on the permanent cautery instruments. This piece would have to be identified and retrieved in order to completely mitigate risk to patient.<br><br>**Instrument thought to be stuck on sterile adapter, release levers not depressed:** |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment B – Risk to Health Appendix

| Use Category | Potential Health Consequence |
|---|---|
| | In the case where a user in not trained or familiar with instrument removal, it could be perceived that the instrument is stuck on the arm. If there is confusion, this could lead to moving the arm when attempting to remove the instrument or even conversion of the procedure to an alternative surgical method |
| Damaged Cables | **Failure of component connection cables (Blue fiber cable):** The *da Vinci* system has multiple components that need to be powered and properly connected for the system to be used. The main system components (Surgeon console, Patient cart and Vision cart) are connected by a fiber optic cable. If this cable is poorly managed and it exposed to abuse (rolled over by OR equipment, etc.) then parts of the system are not able to communicate, and the system is unable. This can cause a procedure to abort post-anesthesia and possibly post-port placement, depending on when the damage is identified. |
| Installation and Use of Sterile Adapters and Drapes | **Improper engagement of the Sterile Adapter to the system or instrument:** The sterile adapter is needed to transfer motion from the robotic arm to the instrument inputs in order to operate the instrument. If the engagement between the sterile adapter and the arm is incomplete, it can cause non-intuitive motion of the instrument. Before the issue is identified, unintended tissue damage can occur due to the non-intuitive motion. If the engagement issue cannot be resolved, abort or conversion of the surgery may be necessary. |
| User Releases Master Tool Manipulator (MTM's) While Head in High Resolution Stereo Viewer (HRSV) | **Releasing masters with head in console:** The surgical masters are balanced to minimize surgeon fatigue during use. However, if the surgeon releases the masters, but keeps his/her head in the console, the masters do not lock in position, and can float unintentionally. If the balance of the masters is off, the masters can move and the instruments will follow. This unintended motion of the instruments can lead to unintended tissue damage. |
| 3rd Party Equipment | **Using wrong ESU connection to the system:** In most ORs there are multiple ESUs and connections. If the wrong connector is used to connect an ESU into the system, the control of the ESU can be incorrect. This can lead to firing of the wrong energy mode and potentially cause unintended tissue damage. While many connectors are not able to be connected to an incorrect ESU that is not compatible, this safety feature is not available for all ESUs and connector cables. |
| Improper ESU Connections | **Connection into proper receptacle:** Most ElectroSurgical Units (ESUs) have a monopolar and a bipolar receptacle. If an instrument is connected to the incorrect receptacle when activated, the energy would be delivered to the incorrect instrument. This could result in energy delivery to unintended tissue structures before the incorrect connections are identified.<br><br>**Incorrect grounding pad placement:** While this pad is not an Intuitive Surgical product, the proper placement of the ground pad is important for proper dispersion of return energy when using monopolar energy. No contact or incomplete contact can cause the inability to deliver energy or cause patient burns at the grounding pad site, respectively. |
| Moving Instrument While Out of View | **Articulation of instrument off screen:** Moving instruments while they are out of the surgeon's field of view can lead to unintended tissue damage and potentially significant patient harm depending on the tissue type at issue. This can happen when a surgeon is trying to identify an instrument that has shifted off screen or when taking control of a 3rd arm off screen.<br><br>**Insertion or removal of an instrument not in view:** |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment B – Risk to Health Appendix

| Use Category | Potential Health Consequence |
|---|---|
| | Inserting instruments into the patient without using direct visualization can lead to unintended tissue damage and potentially significant patient harm, depending on the tissue at issue. There are two reported instances where damage of critical vessels during blind insertion of an instrument resulted in patient death. |
| Surgical Error Unrelated to System Use | **Unintentional tissue damage:** These are instances where surgical error resulted in unintended tissue damage. If unable to be repaired, such damage can lead to serious injury or death. There are two reported instances of patient death, due unintentional tissue damage.<br><br>**Cannula insertion causing damage:** Cannula insertions are common to all minimally invasive surgery and are completed prior to the introduction of the *da Vinci* system to the procedure. The camera cannula is not a device provided by Intuitive Surgical. This cannula is sometimes introduced without direct visualization. There are two reported instances where incorrect camera cannula insertion resulted in patient death. |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment C – Identification of Labeling Changes

Table of Contents


| Section Name | Page |
|---|---|
| Improper Electrosurgical (ESU) Use | 2-8 |
| Improper/Unplugged System Connections | 8-10 |
| Procedure for Converting While Instrument is Grasping Tissue | 10-21 |
| Unintended Use of Instruments | 21-22 |
| Improper Installation of Tip Accessory | 22-24 |
| Instrument to Instrument Interactions | 24-28 |
| Incorrect Vision Settings | 28-29 |
| Instrument Removal | 29-30 |
| Damaged Cables | 30-31 |
| Installation and Use of Sterile Adapters and Drapes | 31-33 |
| User Releases Master Tool Manipulator (MTM's) While Head in High Resolution Stereo Viewer (HRSV) | 33 |
| 3rd Party Equipment | 33-37 |
| Improper ESU Connections | 37-40 |
| Moving Instrument While Out of View | 40-42 |
| Surgical Error Unrelated to System Use | 42-47 |

## Attachment C – Identification of Labeling Changes

# Improper ESU Use

| Manual | Location | Original | Change |
|---|---|---|---|
| *da Vinci* Si System Manual | Section 1.4 | a. CAUTION: The Intuitive Surgical electrosurgical instruments are designed for use with a maximum peak voltage of 3kV (6kV peak-to-peak). Do not use settings on the ESU that exceed a 3kV peak. Do not attempt to use the footswitch on the Surgeon Console with ESUs that are not compatible with the da Vinci Si System. Consult with your Intuitive Surgical representative regarding compatible models.<br><br>b. Always use the lowest output setting that achieves the desired surgical effect. | a. Updated Caution:<br>CAUTION: The Intuitive Surgical **monopolar** electrosurgical instruments are designed for use with a maximum peak voltage of 3kV (6kV peak-to-peak). Do not use settings on the ESU that exceed a 3kV peak. Do not attempt to use the footswitch on the Surgeon Console with ESUs that are not compatible with the da Vinci Si System. Consult with your Intuitive Surgical representative regarding compatible models. **A table in the Instruments and Accessories User Manual lists compatible generators, modes and maximum power settings to stay below the 3kV peak limit.**<br><br>b. Updated bulleted list, second bullet:<br>**For monopolar instruments,** always use the lowest output setting that achieves the desired surgical **effect, while staying within 3kV maximum peak voltage. Maximum power levels to stay below this limit are listed in a table in the Instruments and Accessories User Manual.** |
| *da Vinci* Si System Manual | Section 4.4 | Step 1 in "To connect an auxiliary device…" section:<br>1. Plug the auxiliary device end of the cable into the corresponding channel(s) on the device. | Added to Step 1 in "To connect an auxiliary device…" section:<br>1. Plug the auxiliary device end of the cable into the corresponding channel(s) on the device. **Tighten the screw lock completely to ensure that the cable is fully connected.** |
| *da Vinci* Si System | Section 4.4 | Step 2 in "To connect an auxiliary device…" section: Plug the system end | Added to Step 2 in "To connect an auxiliary device…" section: Plug the system end of the cable into any of the three Energy receptacles on the back of the |

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| Manual | | of the cable into any of the three Energy receptacles on the back of the Core (Figure 4.14). | Core (Figure 4.14). **Align the red dot on the cable connector with the red dot to the right of the receptacle. You should hear an audible click when the cable engages properly. Gently pull on the cable connector to verify that the cable is fully seated. When the ESU and system are turned on, the corresponding LED indicator will turn on.** |
| Instruments and Accessories User Manual | Section 3.3 | "Table 3-3 Maximum ESU Power Settings to Stay Below 3kV Limit" | "Table 3-3 Maximum ESU Power Settings to Stay Below the Monopolar Instrument 3kV Limit **for Approved ESUs and Monopolar Coag Modes**" |
| Instruments and Accessories User Manual | Section 3.2 | 3.2 Special Configuration Instructions | 3.2 **Proper** Configuration Instructions |
| Instruments and Accessories User Manual | Section 3.3 | N/A | Added "Recommended use of monopolar Cut mode" section:<br><br>**Recommended use of monopolar Cut mode**<br><br>**1.Any monopolar Cut mode can be used; however, use the lowest power setting that achieves the desired effect.**<br><br>**2. Apply energy for the minimum time necessary to achieve the desired effect.**<br><br>**3. Ensure that instrument tips are not glowing red and that there is not a blue plasma cloud surrounding the tips. The power setting is too high if these indications are observed.** |

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 3.3 | N/A | Added:<br>**Bipolar instruments are rated for a maximum peak voltage of 500V. Any bipolar Coag mode is acceptable except Forced Coag on the ERBE VIO 300 D generator and Macro on the ConMed System 5000 generator.** |
| Instruments and Accessories User Manual | Section 3.3 | N/A | Added in Table 3-3:<br>• In table columns: Asterisk next to Megadyne<br>• Below the table: ***Not approved for use with da Vinci Si** |
| Instruments and Accessories User Manual | Section 3.2 | N/A | Added label, "**AUS OFF must be lit**" and pointer arrows for Figure 3.1.<br>Sentence added: **Ensure that the Auto Start Off indicator is lit (see Figure 3.1). If the Auto Start Off indicator (AUS OFF) is not lit, press the arrow button below it to select it.** |
| Instruments and Accessories User Manual | Section 3.3 | CAUTION: Please refer to the individual ESU manufacturer's Operator's Manuals for operating instructions. Set the ESU to bipolar output. Set the power as low as possible to achieve adequate hemostasis. | Added to Caution, "Any bipolar coag mode is acceptable."<br>CAUTION: Please refer to the individual ESU manufacturer's Operator's Manuals for operating instructions. Set the ESU to bipolar output**. Any bipolar coag mode is acceptable except Forced Coag on the ERBE VIO 300 D generator and Macro on the ConMed System 5000 generator.** Set the power as low as possible to achieve adequate hemostasis. |
| Instruments and Accessories User Manual | Section 3.2 | Step 3 in "To Select Single Footswitch for BIPOLAR":3. On the next screen, select the upper left soft button for single footswitch. When selected, the circle next to the soft button is filled green, as shown: | Added to Step 3 in "To Select Single Footswitch for BIPOLAR":3. On the next screen, select the upper left soft button for single footswitch. **Do not select either of the Auto Start modes.** When selected, the circle next to the soft button is filled green, as shown: |

## Attachment C – Identification of Labeling Changes

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 3.3 | WARNING: Do not exceed the 3kV peak limit. Doing so may result in electrical arcs and alternate site burns. | Added to Warning:<br>WARNING: Do not exceed the 3kV peak limit **with monopolar instruments**. Doing so may result in electrical arcs and alternate site burns**. See Table 3-3 for maximum ESU power settings to stay below this limit for monopolar Coag mode. Do not use any generator or monopolar Coag mode not listed in this table.** |
| Instruments and Accessories User Manual | Section 3.3 | WARNING: Excessive power levels may result in instrument malfunction and possible patient or user injury. Reduce power setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of end effector (e.g., end effector glowing red). | Added to Warning:<br>WARNING: Excessive power levels may result in instrument malfunction and possible patient or user injury. Reduce power setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of end effector (e.g., end effector glowing red **or emitting a blue plasma cloud**). |
| Instruments and Accessories User Manual | Section 3.2 | N/A | Added Warning:<br>**WARNING: Ensure that Auto Start is not selected for Bipolar modes. To properly configure the ERBE ICC 350, ERBE VIO 300D, and Covidien Force Triad for use with the surgeon console footswitch, follow the instructions below.** |
| Instruments and Accessories User Manual | Section 3.1 | N/A | Added Warning:<br>**WARNING: Make sure the electrosurgical unit (ESU or generator) is properly functioning before connecting it and using it with the system.** |
| Instruments and Accessories User Manual | Section 3.3 | The EndoWrist instruments are intended for electrosurgical applications. They are designed for a maximum peak voltage of 3kV in the | The EndoWrist **monopolar** instruments are intended for electrosurgical applications. They are designed for a maximum peak voltage of 3kV in the "coagulate" and "cut" settings with validated ESUs. **Refer to the ESU's manual** |

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| | | "coagulate" and "cut" settings with validated ESUs. | **for maximum peak voltage specifications.** |
| Instruments and Accessories User Manual | Section 3.3 | Table 3-2. Maximum ESU Power Settings to Stay Below 3kV Limit | Updated content for the ConMed System 5000 ESU. |
| Instruments and Accessories User Manual | Section 3.3 | The corresponding maximum ESU power settings to stay below the 3kV limit are as follows: | Updated to:<br>The **approved ESUs, Monopolar Coag Modes and** corresponding maximum ESU power settings to stay below the **monopolar instrument** 3kV limit are as follows. **Do not use an unapproved ESU or unlisted monopolar coag mode.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Added "Recommended use of monopolar Cut mode" section:<br>**Recommended use of monopolar Cut mode**<br>**1. Any monopolar Cut mode can be used; however, use the lowest power setting that achieves the desired effect.**<br>**2. Apply energy for the minimum time necessary to achieve the desired effect.**<br>**3. Ensure that instrument tips are not glowing red and that there is not a blue plasma cloud surrounding the tips. The power setting is too high if these indications are observed.** |
| Single-Site OUS Manual | Section 10.2 | WARNING: Do not exceed the 500V peak limit. Doing so may result in electrical arcs and alternate site burns. | WARNING: Do not exceed the 500V peak limit **with bipolar instruments**. Doing so may result in electrical arcs and alternate site burns. **See Table 10-5 for maximum ESU power settings to stay below this limit. Do not use any generator or mode not listed.** |

## Attachment C – Identification of Labeling Changes

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| Single-Site OUS Manual | Section 10.2 | Monopolar Cautery Settings:<br>Set the ESU to the desired monopolar output. Set the power as low as possible to achieve adequate hemostasis. | Added sentences under Monopolar Cautery Settings:<br>Set the ESU to the desired monopolar output. **Keep the monopolar coag settings below the maximum settings in Table 10-4 below.** Set the power as low as possible to achieve adequate hemostasis. **Any monopolar Cut mode can be used; however, follow the Recommended use of monopolar Cut mode.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Added Warning:<br>**WARNING: Ensure that the ESU is properly functioning prior to connecting and using with the system.** |
| Single-Site OUS Manual | Section 10.2 | The corresponding maximum ESU power settings to stay below the 500V peak limit are as follows. | Added:<br>The **approved ESUS, Bipolar Coag Modes and** corresponding maximum ESU power settings to stay below the 500V peak limit are as follows. **Do not use an unlisted ESU or mode.** |
| Single-Site OUS Manual | Section 10.2 | The corresponding maximum ESU power settings to stay below the 3kV peak limit are as follows. | Added:<br>The **approved ESUs, Monopolar Coag Modes and** corresponding maximum ESU power settings to stay below the 3kV peak limit are as follows. **Do not use an unlisted ESU or Monopolar Coag mode.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Updated all settings in table 10-4 |
| Single-Site OUS Manual | Section 10.2 | Table 10-4 Title: "Table 10-4 Maximum ESU Power Settings to Stay Below 3kV Peak" | Table 10-4 Added to end of title: "Table 10-4 Maximum ESU Power Settings to Stay Below 3kV Peak **Limit for approved ESUs and Monopolar Coag modes**" |

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| Single-Site OUS Manual | Section 10.2 | Table 10-5 Title "Table 10-5 Maximum ESU Power Settings to Stay Below 500V Peak Limit" | Table 10-5 Added to end of title "Table 10-5 Maximum ESU Power Settings to Stay Below 500V Peak Limit **for Approved ESUs and Bipolar Modes**" |
| Single-Site OUS Manual | Section 10.2 | The Single-Site Instruments are intended for electrosurgical applications. They are designed for a maximum peak voltage of 3kV in the "coagulate" and "cut" settings with validated ESUs. Refer to the ESU's manual for maximum peak voltage specifications. | Updated to be specific for Monopolar instruments:<br>The Single-Site **monopolar** Instruments are intended for electrosurgical applications. They are designed for a maximum peak voltage of 3kV in the "coagulate" and "cut" settings with validated ESUs. Refer to the ESU's manual for maximum peak voltage specifications. |
| Single-Site OUS Manual | Section 10.2 | WARNING: Do not exceed the 3kV peak limit. Doing so may result in electrical arcs and alternate site burns. See Table 10-4 below for maximum ESU power settings to stay below this limit. Do not use any generator or monopolar coag mode not listed. | Updated Warning to be specific for Monopolar instruments:<br>WARNING: Do not exceed the 3kV peak limit **with monopolar instruments**. Doing so may result in electrical arcs and alternate site burns. See Table 10-4 below for maximum ESU power settings to stay below this limit. Do not use any generator or monopolar coag mode not listed. |
| **Improper/Unplugged System Connections** | | | |
| **Manual** | **Location** | **Original** | **Change** |

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| *da Vinci* Si System Manual | Section 4 | N/A | Added Note: **Note: The only connections you should access on the back of the Vision Cart are the power cords, blue system cables, auxiliary device cables, and audio/video cables as described in this chapter. Other cables on the back of the Vision Cart should remain connected at all times and should only be accessed by authorized ISI personnel.** |
| *da Vinci* Si System Manual | Section 4.5 | N/A | Figure 4.15 – Added green highlight box around the video out and audio in/out sections too. This way anything the user can touch is green and anything they can't is red. |
| *da Vinci* Si System Manual | Section 4.5 | Note: Connectors on the Core (and other components on the Vision Cart) labeled with gray text on a dull background, as those indicated by red boxes in Figure 4.15 above, are connected as necessary by authorized ISI personnel when they install and/or service the system. Therefore no instructions are provided for connecting them in this user manual, although the labels themselves are described in Appendix G: Symbols, Icons and Text Messages Reference. | Added to Note, "Do not unplug any of these connections.":<br>Note: Connectors on the Core (and other components on the Vision Cart) labeled with gray text on a dull background, as those indicated by red boxes in Figure 4.15 above, are connected as necessary by authorized ISI personnel when they install and/or service the system. Therefore no instructions are provided for connecting them in this user manual, although the labels themselves are described in Appendix G: Symbols, Icons and Text Messages Reference. **Do not unplug any of these connections.** |
| *da Vinci* Si System Manual | Section 5.2 | N/A | Added Figure 5.2 Circuit breaker switches on ("I") for main components. Images showing location/look of main circuit breakers. |
| *da Vinci* Si System | Section 5.2 | Step 3 in "Check AC Power Connections": | Added to Step 3 in "Check AC Power Connections" section:<br>3. On the Vision Cart, confirm that each of its component power switches - for |

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| Manual | | 3. On the Vision Cart, confirm that each of its component power switches - for the Core, Camera Control Unit and Illuminator - is correctly set to the on position (indicated by "I" on the switch). Also confirm that each Vision Cart component power cord is plugged into the integrated Vision Cart power strip. | the Core, Camera Control Unit and Illuminator - is correctly set to the on position (indicated by "I" on the switch). **These components are not intended to be turned off or disconnected at any time unless you are directed to do so by Intuitive Surgical Product Support.**Also confirm that each Vision Cart component power cord is plugged into the integrated Vision Cart power strip. |
| Vessel Sealer User Manual | Section 1.6 | Note: Do not turn off the rear power switch on the ICB unless directed to do so by Intuitive Surgical Product Support.<br><br>*ICB – Instrument Control Box | Updated Note:<br>Note: Do not turn off the rear power switch **or disconnect any cables** on the ICB unless directed to do so by Intuitive Surgical Product Support. |

## Procedure for Converting While Instrument is Grasping Tissue

| Manual | Location | Original | Change |
|---|---|---|---|
| *da Vinci* S System Manual | Section 8.4 | N/A | Added Grip Release Warning:<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* S System Manual | Section 8.4 | N/A | Added Grip Release Warning:<br>**WARNING: Do not reuse an instrument that has had its grip released with the instrument release kit. Reusing an instrument after use of the instrument release kit could result in critical failure of the instrument and injury to the patient.** |
| *da Vinci* S System Manual | Section A.3 | N/A | Added Note:<br>**If the system is in a fault state while converting to open surgery, the Patient Cart will still allow use of the port clutch buttons. If the system loses all power, the arms and setup joints may be overpowered to move the arms as necessary.** |
| *da Vinci* S System Manual | Section 11.2 | N/A | Added Section "Instrument Release Kit":<br>**Instrument Release Kit**<br>**Clean and sterilize the instrument release kit in the same way as the grip release tool. For grip release tool cleaning and sterilization instructions, refer to the Reprocessing Instructions (PN 550875).** |
| *da Vinci* S System Manual | Section A.3 | N/A | Conversion to Open Surgery section, added information for disconnecting cannulae and moving the instrument and camera. |
| *da Vinci* S System Manual | Section 8.4 | N/A | Updated Grip Release section:<br>• Referenced Emergency Stop section in Appendix A.<br>• Updated procedure to release the grips |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added Figure 9.13 Grip Release Socket. 8mm & 5mm Instruments diagrams. |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* S System Manual | Section 8.4 | N/A | Added Figure 8.10 Grip Release Socket. 8mm & 5mm Instruments diagrams. |
| *da Vinci* Si System Manual | Section A.2 | Step 1 in "Restarting the System During a Procedure" section:<br>1. Completely remove all instruments from the system. The endoscope does not need to be removed. | Added sentence to end of Step 1 in "Restarting the System During a Procedure" section:<br>1. Completely remove all instruments from the system. The endoscope does not need to be removed**. If an instrument is grasping tissue, follow the grip release instructions in Chapter 9, Grip Release, on page 9-13.** |
| *da Vinci* Si System Manual | Section 9.4 | Step 2 in "Emergency Grip Release" section:<br>"…Small Clip Appliers" | Added to (now) Step 3 in " Grip Release" section:<br>"…8 mm Clip Appliers **and Harmonic Instruments**" |
| *da Vinci* S System Manual | Section 8.4 | Step 2 in "Emergency Grip Release" section:<br>"…Small Clip Appliers" | Added to (now) Step 3 in " Grip Release" section:<br>"…8 mm Clip Appliers **and Harmonic Instruments**" |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added Warning:<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |
| *da Vinci* S System Manual | Section 8.4 | N/A | Added Warning:<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* Si System Manual | Section A.2 | Emergency Stop<br>Press the red Emergency Stop button on the right-side pod of the Surgeon Console should it be necessary to stop system operation at any time. When you press Emergency Stop, the system classifies it as a recoverable fault, which you can override by pressing Recover on the touchpad or touchscreen. | Changed Emergency Stop content:<br>Emergency Stop<br>Press the red Emergency Stop button should it be necessary to stop system operation at any time. **The Emergency Stop button will cease robotic control of the instruments and endoscope. The instruments and endoscope will stay in their last commanded position.**<br><br>**If the instrument grips are closed when the Emergency Stop button is pressed, the grips will remain closed. However, the gripping force of the instrument may decrease.**<br><br>**Pressing Emergency Stop initiates** a recoverable fault, which you can override by pressing Recover on the touchscreen or touchpad. **The Emergency Stop button illuminates when pressed and remains illuminated until the fault is recovered.** |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* S System Manual | Section A.2 | Emergency Stop<br>Press the red Emergency Stop button on the right-side pod of the Surgeon Console should it be necessary to stop system operation at any time. When you press Emergency Stop, the system classifies it as a recoverable fault, which you can override by pressing Recover on the touchpad or touchscreen. | Changed Emergency Stop content:<br>Emergency Stop<br>**An EMERGENCY STOP button is provided on the right-side pod of the Surgeon Console should system operation be required to stop at any time.** Press the red Emergency Stop button should it be necessary to stop system operation at any time. **The Emergency Stop button will cease robotic control of the instruments and endoscope. The instruments and endoscope will stay in their last commanded position.**<br><br>**If the instrument grips are closed when the Emergency Stop button is pressed, the grips will remain closed. However, the gripping force of the instrument may decrease.**<br><br>**Pressing Emergency Stop initiates a** recoverable fault, which you can override by pressing **FAULT OVERRIDE** on the touchscreen or touchpad. |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* Si System Manual | Section A.3 | "Conversion to Open Surgery Section":A.3 Conversion to Open SurgeryIf a situation arises where a conversion to open surgery is required, perform the followingsteps to remove the system from the patient: 1. Remove the instruments and endoscope from the patient.2. Disconnect the cannulae from the instrument and camera arms.3. Move the instrument and camera arms away from the patient. Note: If the system is in an error state while converting to open surgery, the Patient Cart will still allow use of the port clutch buttons. If the system loses all power, the arms and setup joints may be overpowered to move the arms as necessary. | Updated "Conversion to Open Surgery Section":<br>A.3 Conversion to Open Surgery<br>If a situation arises where a conversion to open surgery is required, perform the following steps to remove the system from the patient:<br>1. Remove the instruments and endoscope from the patient. Note the following:<br>**Note: Whenever possible, use Surgeon Console control to release the instrument grips.**<br>a. In case of system failure while the instrument is grasping tissue, the grips can be manually opened by following the grip release instructions, see Grip Release on page 9-13 (Chapter 9, Patient Cart Use).<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.**<br>**WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.**<br>2. Disconnect the cannulae from the instrument and camera arms.<br>3. Move the instrument and camera arms away from the patient.<br>**Note: If the system is in a fault state while converting to open surgery, the Patient Cart will still allow use of the port clutch buttons. If the system loses all power, the arms and setup joints may be overpowered to move the arms as necessary.** |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* Si System Manual | Section A.3 | "Conversion to Open Surgery Section":A.3 Conversion to Open SurgeryIf a situation arises where a conversion to open surgery is required, perform the followingsteps to remove the system from the patient: 1. Remove the instruments and endoscope from the patient.2. Disconnect the cannulae from the instrument and camera arms.3. Move the instrument and camera arms away from the patient. Note: If the system is in an error state while converting to open surgery, the Patient Cart will still allow use of the port clutch buttons. If the system loses all power, the arms and setup joints may be overpowered to move the arms as necessary. | **A.3 Conversion to Open Surgery**<br>If a situation arises where a conversion to open surgery is required, perform the following steps to remove the system from the patient:<br>1. Remove the instruments and endoscope from the patient. Note the following:<br>**Note: Whenever possible, use Surgeon Console control to release the instrument grips.**<br>**a. In case of system failure while the instrument is grasping tissue, the grips can be manually opened by following the grip release instructions, see Grip Release on page 9-13 (Chapter 9, Patient Cart Use).**<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.**<br>**WARNING: Rotating the grip release tool too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.**<br>2. Disconnect the cannulae from the instrument and camera arms.<br>3. Move the instrument and camera arms away from the patient.<br>Note: If the system is in a **fault** state while converting to open surgery, the Patient Cart will still allow use of the port clutch buttons. If the system loses all power, the arms and setup joints may be overpowered to move the arms as necessary. |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added Grip Release Note: **Note: The EndoWrist instrument release kit (PN 381199) includes a grip release tool attached to illustrated instructions for quick-reference. Be sure to keep a sterile instrument release kit in an accessible location.** |
| *da Vinci* Si System Manual | Section 9.4<br>Section A.3 | N/A | Added Grip Release Note:<br>**Note: Whenever possible, use Surgeon Console control to release the** |

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| | | | **instrument grips.** |
| *da Vinci* Si System Manual | Section 9.4<br>Section A.3 | N/A | Added Grip Release Warning:<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added Grip Release Warning:<br>**WARNING: Do not reuse an instrument that has had its grip released with the instrument release kit. Reusing an instrument after use of the instrument release kit could result in critical failure of the instrument and injury to the patient.** |
| *da Vinci* Si System Manual | Section 9.4<br>Section A.3 | N/A | Added Grip Release Warning:<br>**WARNING: Rotating the grip release wrench too far and/or in the incorrect direction can cause unintended instrument motion or damage to the grip release mechanism.** |
| *da Vinci* Si System Manual | Section 12.2 | N/A | Added Instrument Release Kit section:<br>**Clean and sterilize the instrument release kit in the same way as the grip release tool. For grip release tool cleaning and sterilization instructions, refer to the Reprocessing Instructions (PN 550875).** |

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| *da Vinci* Si System Manual | Section 9.4 | N/A | Updated Grip Release Warnings, instructions, and terminology, including removal of Emergency from Grip Release heading.<br>Updated Steps to clarify to always use visualization, to rotate approximately 1/4th turn, to carefully turn the tool, to support the instrument arm before clutching, and not to reuse the instrument after grip release. |
| Instruments and Accessories User Manual | Section 2.1<br>Section 5.1<br>Section 6.1<br>Section 7.1<br>Section 8.1<br>Section 9.1<br>Section 11.1 | N/A | Added Warning:<br>**• Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |
| Instruments and Accessories User Manual | Section 8.1<br>Section 9.1 | WARNING: In case of system failure while this instrument is grasping tissue, the grasping jaw can be opened manually by inserting the emergency grip release or Allen wrench into the proximal hole in the instrument housing and turning counter-clockwise to release. | Updated Warning:<br>In case of system failure while this instrument is grasping tissue, the **grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning clockwise. Squeeze the release levers and withdraw the instrument. Use visualization of surgical site when inserting the grip release wrench, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 2.1 | WARNING: In case of system failure while the instrument is grasping tissue, the grip (jaw) can be opened manually by inserting the emergency grip release or an Allen wrench into the proximal hole in the instrument housing. Squeeze the release levers and carefully withdraw the instrument. | Updated Warning:<br>WARNING: In case of system failure while the instrument is grasping tissue, the **grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning.** Squeeze the release levers and withdraw the instrument. **Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |
| Instruments and Accessories User Manual | Section 6.1<br>Section 7.1 | WARNING: In case of system failure while the instrument is grasping tissue, the grip (jaw) can be opened manually by inserting the emergency grip release or an Allen wrench into the proximal hole in the instrument housing. Squeeze the release levers and carefully withdraw the instrument. | Updated Warning:<br>WARNING: In case of system failure while **these instruments are grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning.** Squeeze the release levers and withdraw the instrument. **Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |
| Instruments and Accessories User Manual | Section 11.1 | WARNING: In case of system failure while the instrument is grasping tissue, the grip (jaw) can be opened manually by inserting the emergency grip release or an Allen wrench into the proximal hole in the instrument housing. Squeeze the release levers and carefully withdraw the instrument. | Updated Warning:<br>WARNING: In case of system failure while **this** instrument is grasping tissue, the **grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning.** Squeeze the release levers and withdraw the instrument. **Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |
| Single-Site OUS | Section 9.2 | N/A | Added Grip Release section. |

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| Single-Site OUS Manual | Section 13.2 | N/A | Added Warning: **WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |
| Single-Site OUS Manual | Section 12.1 | WARNING: In case of system failure while this instrument is grasping tissue, the jaws can be opened manually by inserting the emergency grip release or Allen wrench into the proximal hole in the instrument housing. Squeeze the release levers and carefully withdraw the instrument. | Updated Warning:<br>WARNING: In case of system failure while **these instruments are grasping tissue, the grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning.** Squeeze the release levers and carefully withdraw the instrument. **Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |
| Single-Site OUS Manual | Section 9.2<br>Section 13.2 | WARNING: In case of system failure while this instrument is grasping tissue, the jaws can be opened manually by inserting the emergency grip release or Allen wrench into the proximal hole in the instrument housing. Squeeze the release levers and carefully withdraw the instrument. | Updated Warning:<br>WARNING: In case of system failure while this instrument is grasping tissue, the **grips can be manually opened by inserting the grip release tool into the grip release hole in the instrument housing and carefully turning.** Squeeze the release levers and carefully withdraw the instrument. **Use visualization of surgical site when inserting the grip release tool, opening jaws, clearing jaws from tissue, and removing the instrument from the system.** |

## Attachment C – Identification of Labeling Changes

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| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Grip Release instructions.<br>(Basis for instruction is from the IS3000 System user manual content, with new instruction on how to use the thumbwheel for grip release, which is specific to the Vessel Sealer instrument.) |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Grip Release Note:<br>**Note: The EndoWrist instrument release kit (PN 381199) includes a grip release tool attached to illustrated instructions for quick-reference. Be sure to keep a sterile instrument release kit in an accessible location.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Grip Release Note:<br>**Note: Whenever possible, use Surgeon Console control to release the instrument grips.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: After removal of the instrument during a system or instrument failure, use caution when opening the jaws using the thumbwheel, to avoid potential injury due to an exposed cutting blade.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: Do not use the grip release tool on the Vessel Sealer instrument.** |

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| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: In case of system failure while the instrument is grasping tissue, open the instrument jaws by turning the thumbwheel in the direction of the arrow to release the tissue. Once the tissue is released, close the jaws. (In this case, it is OK to close the jaws on an exposed blade.) Squeeze the release levers and carefully withdraw the instrument.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | **For additional information regarding the Emergency Stop button, see the da Vinci Si System User Manual, PN 550650.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added: "**Perform these steps while visualizing the surgical site**" |

# Unintended Use of Instruments

| **Manual** | **Location** | **Original** | **Change** |
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| Instruments and Accessories User Manual | Section 13.2 | N/A | Added image for "Figure 13.3 Snap-fit Blade installed incorrectly" and content. |
| Instruments and Accessories User Manual | Section 13.2 | Step 3 in "Insertion Tool" section:<br>3.Insert the scalpel blade into the wrist until it is firmly seated, as shown. | Added sentence to Step 3 in "Insertion Tool" section:<br>3. **There should be no gap between the accessory tip base and the instrument (see Figure 13.4 for improperly seated Snap-Fit Blade).** |
| Instruments and Accessories User Manual | Section 13.2 | Step 1 in "Blade Protector" section:<br>1. Before inserting a scalpel instrument into an instrument arm cannula, slide the blade protector on to the | Updated Step 1 in "Blade Protector" section:<br>1. Before inserting a scalpel instrument into an instrument arm cannula, slide **the wider end of** the blade protector on to the instrument shaft until the scalpel blade is completely covered **by the sleeve of the blade protector** (Figure |

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| | | instrument shaft until the scalpel blade is completely covered (Figure 13.4). | 13.5). |
| Instruments and Accessories User Manual | Section 13.1 | N/A | Added Warning:<br>**Warning: The Snap-fit Scalpel instrument, used in combination with the Snap-fit 15° Blue Blade or Snap-Fit Paddle Blade disposable accessory tips, should not be used to cut or incise large organs or tissue. If used in this manner, the accessory tip may be damaged and fall into the patient.** |
| Single-Site OUS Manual | Section 14.2 | N/A | Added sentence, "**Do not push the instrument into cartilage, bone or other hard objects."** in Intraoperative Use section. |
| Vessel Sealer User Manual | Section 1.5 | N/A | Added Warning:<br>**WARNING: Do not use the Vessel Sealer on bone or other hard surfaces.** |

## Improper Installation of Tip Accessory

| **Manual** | **Location** | **Original** | **Change** |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 17.2 | N/A | Added in "Instrument and Laser Use" section:**If the instrument is removed and re-installed, loosen the Touhy-Borst adapters, withdraw the sheath and fiber into the instrument tip, and re-tighten the Touhy-Borst adapters prior to re-installing and inserting the instrument though the cannula. Follow steps 9-11 to re-install the instrument.** |

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 13.2 | Step 4 in "Blade Protector" section:<br>4. Immediately before removing a scalpel instrument, slide the blade protector through the cannula seal towards the instrument tip. | Added sentence to Step 4 in "Blade Protector" section:<br>4. Immediately before removing a scalpel instrument, slide the blade protector through the cannula seal towards the instrument tip. **Be sure to remove the blade protector along with the instrument. If the blade protector remains in the cannula seal, loss of insufflation will occur.** |
| Instruments and Accessories User Manual | Section 17.2 | Step 10 in "Assembly Instructions" section:<br>10. Advance the fiber until it protrudes 1-2 mm from the tip of the laser sheath. | Added to Step 10 in "Assembly Instructions" section:<br>10. **Under endoscopic visualization, advance the sheath until it protrudes approximately 2mm from the tip of the instrument.** Advance the fiber until it protrudes 1-2 mm from the tip of the laser sheath. |
| Instruments and Accessories User Manual | Section 17.2 | Step 11 in "Assembly Instructions" section:<br>11. Tighten the proximal and sliding Touhy-Borst adapters when desired fiber position is reached. | Added to Step 11 in "Assembly Instructions" section:<br>11. Tighten the proximal and sliding Touhy-Borst adapters when desired fiber position is reached. **Verify that the fiber and sheath are properly secured. Gently pull back on the sheath exiting the instrument housing and confirm no movement of the sheath occurs, Gently pull back on the fiber exiting the sheath. No motion of the fiber should occur.** |
| Instruments and Accessories User Manual | Section 19.2 | Step 3 in "Intraoperative Use":<br>3. Insert the obturator fully into the cannula. | Added to Step 3 in "Intraoperative Use":<br>3. Insert the obturator fully into the cannula**. If using a latching obturator, ensure that the latches are fastened over the rim of the cannula. If using a non-latching obturator, ensure that the obturator is seated firmly against the seal and that the tip of the obturator appears at the distal end of the cannula sleeve.** |

## Attachment C – Identification of Labeling Changes

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 17.2 | Step 8 in "Assembly Instructions" section:<br>8. Slide the sliding Touhy-Borst adapter along the sheath and twist-lock the luer connector onto the female luer at the back of the instrument. | Added to Step 8 in "Assembly Instructions" section:8. Slide the sliding Touhy-Borst adapter along the sheath and twist-lock the luer connector onto the female luer at the back of the instrument. **Tighten the Touhy-Borst adapter. Verify that the sheath is properly secured within the instrument by gently pulling back on the sheath exiting the instrument housing. When properly secured, no movement of the sheath will occur.** |
| Instruments and Accessories User Manual | Section 17.2 | Step 7 in "Assembly Instructions" section:<br>7. Advance the sheath into the instrument until it extends 2 mm past the tip of the instrument. | Updated Step 7 in "Assembly Instructions" section:<br>7. Advance the sheath into the instrument until it extends past the tip. **Retract the sheath slightly, until it is just inside of the tip.** |
| Single-Site OUS Manual | Section 7.1 | Step 1:<br>Insufflate the abdomen and insert the camera cannula using the blunt obturator. | Added at the end of Step 1:<br>Insufflate the abdomen and insert the camera cannula using the blunt obturator. **When the cannula is at the correct insertion depth, the top line on the cannula will be level with the top of the Single-Site port.** |
| Single-Site OUS Manual | Section 15.2 | Step 3 in Intraoperative Use section:<br>3. Insert the obturator fully into the cannula. | Added to Step 3 in Intraoperative Use section:<br>3. Insert the obturator fully into the cannula. **Ensure that the obturator is seated firmly against the seal, the latches are fastened over the rim of the cannula, and the tip of the obturator appears at the distal end of the cannula sleeve.** |
| Single-Site OUS Manual | Section 15.2 | Step 6 in Intraoperative Use section:<br>“…thick black ring) should be placed within…" to, “…thick black ring) be placed within…" | Updated Step 6 in Intraoperative Use section:<br>“…thick black ring) should be placed within…" to, “…thick black ring) must be placed within…" |

# Instrument to Instrument Interactions

| Manual | Location | Original | Change |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 2.1 | N/A | Added bullet:<br>**Use instruments with care. Avoid contact between instruments intraoperatively and do not use one instrument to apply force to another instrument inside the patient.** |
| Instruments and Accessories User Manual | Section 19.2 | "Visual Inspection": Hold the item up close and visually inspect for defects. Examples of defects include roughedges, dents, or an out-of-round shape. Figure 19.1 below shows examples of defectivecannulae and a cannula that is not defective. | Added in "Visual Inspection":**Hold the item up close and visually inspect for defects. Examples of defects include rough edges, dents, an out-of-round shape, or a bent cannula shaft. Figure 19.1 below shows examples of defective cannulae and a cannula that is not defective.** |
| Instruments and Accessories User Manual | Section 4.2 | N/A | Added Note :<br>**During use, if the blades become contaminated by carbonized tissue, remove the instrument and wipe the blades with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the blades.** |
| Instruments and Accessories User Manual | Section 5.2<br>Section 16.2 | N/A | Added :<br>**During use, if the tip becomes contaminated by carbonized tissue, remove the instrument and wipe the tip with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the tip.** |

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 8.1 | Bullet:<br>Blood and tissue buildup between the blade and insert may result in abnormally high temperatures at the distal end of the insert. To prevent burn injury, remove any visible tissue buildup at the distal end of the insert. | Added to Bullet:<br>**To prevent burn injury, remove any visible tissue buildup at the distal end of the insert by removing the instrument and wiping with moist, sterile gauze.** |
| Instruments and Accessories User Manual | Section 2.2 | N/A | Added Warning:<br>**WARNING: Do not use an instrument to clean debris from another instrument inside the patient. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. To clean an instrument intraoperatively, remove the instrument from the system and wipe the instrument tip with moist sterile gauze.** |
| Instruments and Accessories User Manual | Section 2.1 | Bullet:<br>Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. | Updated bullet to replace "intraoperatively" to "**inside the patient**":<br>Do not use an instrument to clean debris from another instrument **inside the patient**. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. |
| Single-Site OUS Manual | Section 9.1 | N/A | Added bullet:<br>**Use instruments with care. Avoid contact between instruments intraoperatively and do not use one instrument to apply force to another instrument inside the patient.** |

## Attachment C – Identification of Labeling Changes

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| Single-Site OUS Manual | Section 11.2 | N/A | Added Note:<br>**Note: During use, if the tip becomes contaminated by carbonized tissue, remove the instrument and wipe the tip with a piece of moistened, sterile gauze to remove the tissue. Do not use another instrument to clean the tip.** |
| Single-Site OUS Manual | Section 14.2 | N/A | Added sentence, "**Do not push the instrument into cartilage, bone or other hard objects."** in Intraoperative Use section. |
| Single-Site OUS Manual | Section 9.1 | Bullet:<br>Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. | Updated bullet:<br>Do not use an instrument to clean debris from another **instrument inside the patient**. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. **To clean an instrument intraoperatively, remove the instrument from the system and wipe the tips with sterile moistened gauze.** |
| Single-Site OUS Manual | Section 15.2 | In "Inspection Instructions" section:<br>Before use, inspect the cannulae and obturators for damage or defects. | Updated In "Inspection Instructions" section:<br>Before use, inspect all cannulae and obturators for damage or defects. **Examples of cannula damage include rough edges, dents, an out-of-round shape, or a bent cannula shaft. For more information, see Curved Cannula Inspection on page 53.** |
| Single-Site OUS Manual | Section 11.2 | Inspection Before Use section:<br><br>Inspection Before Use<br><br>Examine the instrument before use. In particular, examine the following components for cracks or flaws: | Updated Inspection Before Use section:<br><br>Inspection Before Use<br><br>**Monopolar Cautery Instrument**<br><br>Examine the **monopolar cautery** instrument before use. **If any damage is** |

| | | | |
|---|---|---|---|
| | | •end effector<br>•the tube insulation<br>•cautery hook tip | **observed, do not use the instrument.** In particular, **look for** the following:<br>**•Cracks or damage on the end effector**<br>**•Cracks on shaft**<br>**•Broken energy cord connector**<br>**•Defects in the metal or plastic components of the accessory tip**<br>**Permanent Cautery Hook**<br>**Examine the permanent cautery hook before use. If you observe cracks or other damage, or if the tip appears loose, do not use the instrument. Examples of damage include: defects on the hook tip, cracks or damage to the piece connecting the tip to the shaft, broken energy cord connector, and cracks or scratches on the shaft.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: Do not use any instrument to clean the Vessel Sealer inside the patient. To clean the jaws intraoperatively, see Intraoperative Cleaning on page 20.** |
| Vessel Sealer User Manual | Section 1.5 | N/A | Added Warning:<br>**WARNING: Do not use the Vessel Sealer on bone or other hard surfaces.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: Use instruments with care. Avoid contact between instruments inside the patient and do not use any instrument to apply force to another instrument inside the patient.** |

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| Vessel Sealer User Manual | Section 1.5 | WARNING: Discontinue use if any abnormality is observed during use. | Updated Warning:WARNING: Discontinue use if any **damage or** abnormality is observed during use. **Examples of instrument damage include broken or bent jaws, scratches or cracks on the instrument shaft, defects on the electrode sealing surface, or cuts/damage to the insulation on the wires.** |
| **Incorrect Vision Settings** | | | |
| **Manual** | **Location** | **Original** | **Change** |
| *da Vinci* Si System Manual | Section 7.4 | Note: To minimize fogging, maintain heating of the endoscope tip by setting the Illuminator intensity to 100% and adjust the brightness of the surgical image using the Illumination slider on the touchpad or touchscreen under Advanced Video Adjustments. | Updated Note:<br>Note: **Both the Brightness slider (video brightness) and the Illuminator slider (lamp intensity) will affect the brightness of the image seen in the stereo viewer.** To minimize fogging, maintain heating of the endoscope tip by setting the Illuminator **slider to maximum and then** adjust image brightness using the **Brightness** slider. **If working close to tissue, decrease the Illuminator intensity using the Illuminator slider, and increase image brightness as necessary using the Brightness slider. If the image is too dark, check both the Illuminator and Brightness sliders, making sure each is far enough to the right, given the working distance of the endoscope tip from tissue.** |
| *da Vinci* Si System Manual | Section 7.4 | N/A | In Advanced Video Adjustments, added bullet:<br>**Restore Factory Settings: Touch to restore all advanced video adjustments to default values, which should be appropriate for most clinical scenarios."** |
| **Instrument Removal** | | | |
| **Manual** | **Location** | **Original** | **Change** |

| | | | |
|---|---|---|---|
| *da Vinci* Si System Manual | Section 9.4 | Instruction Removal Steps:1.Before instrument removal, the Surgeon Console operator should do the following:a. Ensure the instrument tip is free and clear of any patient anatomy.b. Straighten the instrument wrist.c. Open the instrument jaws (instrument removal is difficult with jaws closed).d. Clearly communicate to the Patient Cart operator which instrument to remove. Identify the name of the instrument or the number of the instrument arm (e.g., instrument arm 1, 2, 3).2.Once the instrument is positioned for removal, the Patient Cart operator should squeeze the release levers on the sides of the instrument and pull the instrument out, then clear the sterile adapter. | Updated Instrument Removal steps:<br><br>1.Before instrument removal, the Surgeon Console operator should do the following:<br><br>a. Ensure that the instrument tip is **in view and is free** of any patient anatomy.<br><br>b. Straighten the instrument wrist.<br><br>c. Clearly communicate to the **patient-side assistant** which instrument to remove. Identify the name of the instrument or the number of the instrument arm (e.g., instrument arm 1, 2, 3).<br><br>2. Once the instrument is positioned for removal, the **patient-side assistant** should squeeze the release levers on the sides of the instrument and pull the instrument out. |
| **Damaged Cables** | | | |
| **Manual** | **Location** | **Original** | **Change** |

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|---|---|---|---|
| *da Vinci* Si System Manual | Section 4.2 | Note: The system cables have a fiber-optic core. Care should be taken to avoid bending the cable, as kinks can damage the cable and may prevent system operation. The minimum safe bend radius is 1 inch (2.54 cm). | Added "**Take care to avoid stepping on the cable, since this can damage it.**" to existing Note:Note: The system cables have a fiber-optic core. Care should be taken to avoid bending the cable, as kinks can damage the cable and may prevent system operation. The minimum safe bend radius is 1 inch (2.54 cm). **Take care to avoid stepping on the cable, since this can damage it.** |

## Installation and Use of Sterile Adapters and Drapes

| Manual | Location | Original | Change |
|---|---|---|---|
| *da Vinci* Si System Manual | Section 6.3 | N/A | Added Sterile Adapter Engagement Verification content (below), picture and diagrams:<br><br>**Sterile Adapter Engagement Verification**<br><br>**It is important to ensure the sterile adapter built into the drape is properly engaged with the instrument arm, so the instrument works properly when installed. Follow these steps and best practices to ensure engagement.**<br><br>**After the Sterile Adapter is attached and the discs rotate back and forth, verify the position of the open notch on each disc.**<br><br>**Open Notch Location:**<br><br>**Top Left disc – 7 o'clock**<br><br>**Top right disc – 11 o'clock**<br><br>**Bottom right disc – 3 o'clock** |

| | | | |
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| | | | **Bottom left disc – 10 o'clock**<br><br>**Clockwise from top left:**<br><br>**"7, 11, 3, 10"**<br><br>**The discs should be in this alignment after draping and before installation of an instrument.**<br><br>**Note: Once a sterile adapter is successfully engaged on the arm, it should not need to be removed or reseated until the end of the procedure.If any open notch does not match the position above, use the closed tip of a sterile Kelly Forceps or Hemostat instrument to manual rotate the disc.Rotate the disc in either direction until it clicks into place. The disc should no longer rotate once it is fully engaged. If the sterile adapter does not engage properly, remove & reseat the instrument arm drape.** |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added best practices for instrument installation section:<br><br>**Instrument Installation Best Practices**<br><br>**1. Verify the sterile adapter discs are aligned using the process above before installing an instrument.**<br><br>**2. Do not squeeze the release levers while installing the instrument onto the Sterile Adapter.**<br><br>**3. Do not apply excessive force when installing the instrument.**<br><br>**4. Verify pins on the back of the arm are flush on the arm and not protruding.** |

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| | | | **Troubleshooting Sequence:**<br><br>**1. If the instrument does not engage properly, reseat the instrument.**<br><br>**2. If the problem is not resolved, reseat the sterile adapter using the Sterile Adapter Engagement Verification process on page 6-11.**<br><br>**3. If the problem is not resolved, re-drape the arm.For assistance, contact Technical Support: U.S. 800-876-1310, International +800 0821 2010 or +41 21 821 2020.** |
| **User Releases MTM's While Head in HRSV** | | | |
| **Manual** | **Location** | **Original** | **Change** |
| *da Vinci* Si System Manual | Section 9.4 | N/A | Added Warning:<br>**WARNING: During an instrument exchange, including using Guided Tool Change, the surgeon must not remove his/her hands from the masters until he/she has removed his/her head from the stereo viewer.** |
| **3rd Party Equipment** | | | |
| **Manual** | **Location** | **Original** | **Change** |

## Attachment C – Identification of Labeling Changes

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| *da Vinci* Si System Manual | Section 1.4 | CAUTION: The Intuitive Surgical electrosurgical instruments are designed for use with a maximum peak voltage of 3kV (6kV peak-to-peak). Do not use settings on the ESU that exceed a 3kV peak. Do not attempt to use the footswitch on the Surgeon Console with ESUs that are not compatible with the da Vinci Si System. Consult with your Intuitive Surgical representative regarding compatible models. | CAUTION: The Intuitive Surgical electrosurgical **monopolar** instruments are designed for use with a maximum peak voltage of 3kV (6kV peak-to-peak). Do not use settings on the ESU that exceed a 3kV peak. Do not attempt to use the footswitch on the Surgeon Console with ESUs that are not compatible with the da Vinci Si System. Consult with your Intuitive Surgical representative regarding compatible models. **A table in the Instruments and Accessories User Manual lists compatible generators, modes and maximum power settings to stay below the 3kV peak limit.** |
| Instruments and Accessories User Manual | Section 3.3 | N/A | Added in Table 3-3:<br>• In table columns: Asterisk next to Megadyne<br>• Below the table: ***Not approved for use with da Vinci Si** |
| Instruments and Accessories User Manual | Section 19.1 | N/A | Added Note:<br>**Note: To maintain pneumoperitoneum, ensure that the cannula seal is firmly secured to the cannula. To confirm secure attachment: Ensure that the 8mm Cannula Seal and EndoWrist Stapler Cannula Seal are visibly seated around the circumference of the cannula bowl. Ensure that the 5mm Cannula Seal clicks into place. Ensure that all four tabs on the 8.5-13mm Seal (PN 420206) are over the cannula lip.** |

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 21.1 | "Device Description" section:<br>The disposable seal consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn. The 8 mm seal includes a built-in 5 mm converter to prevent leakage and allow insertion of instruments of different diameters than the main seal. The seal is to be assembled with the Intuitive cannula. To use, attach the disposable seal assembly securely to the top of the cannula. Insert the obturator through the seal into the cannula until the handle of the obturator is seated firmly against the seal, and the tip of the obturator appears at the distal end of the cannula sleeve. | Added sentence in "Device Description" section:<br>The disposable seal consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn. The 8 mm seal includes a built-in 5 mm converter to prevent leakage and allow insertion of instruments of different diameters than the main seal. The seal is to be assembled with the Intuitive cannula. To use, attach the disposable seal assembly securely to the top of the cannula. **Ensure that the seal is visibly seated around the circumference of the cannula bowl.** Insert the obturator through the seal into the cannula until the handle of the obturator is seated firmly against the seal, and the tip of the obturator appears at the distal end of the cannula sleeve. |
| Instruments and Accessories User Manual | Section 22.2 | Step 1 in "22.2 Instructions for Use" section:1.Attach the seal to the reducer by aligning it axially with the reducer, and sliding the pins of the cannula reducer into the slots on the seal. Rotate the seal clockwise to lock into place. See Figure 22.1. | Added to Step 1 in "22.2 Instructions for Use" section:<br>1.Attach the seal to the reducer by aligning it axially with the reducer, and sliding the pins of the cannula reducer into the slots on the seal. Rotate the seal clockwise to lock into place. **You will hear a click once the cannula seal is locked in place.** See Figure 22.1. |

## Attachment C – Identification of Labeling Changes

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 3.3 | Table 3-3: | Edited Table 3-3:<br>Changed all instances of “ValleyLab” to “Covidien” and updated content for ConMed System 5000 |
| Instruments and Accessories User Manual | Section 3.3 | "Table 3-3 Maximum ESU Power Settings to Stay Below 3kV Limit" | "Table 3-3 Maximum ESU Power Settings to Stay Below **the Monopolar Instrument** 3kV Limit **for Approved ESUs and Monopolar Coag Modes**" |
| Instruments and Accessories User Manual | Section 3.3 | "The corresponding maximum ESU power settings to stay below the 3kV limit are as follows:" | Updated to:<br>The **approved ESUs, Monopolar Coag Modes and** corresponding maximum ESU power settings to stay below the **monopolar instrument** 3kV limit are as follows. **Do not use an unapproved ESU or unlisted monopolar coag mode.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Added Note under Monopolar Cautery Settings section:<br>**Note: Refer to the Instruments and Accessories User Manual (PN 550675) for appropriate instrument cord connections and for proper setup instructions pertaining to use of the ERBE ICC 350, ERBE VIO 300D and Covidien Force Triad generators.** |
| Single-Site OUS Manual | Section 15.2 | Step 2 in Intraoperative Use section:<br>2. Using sterile technique, attach the appropriate sterile cannula seal to the cannula. | Added to Step 2 in Intraoperative Use section:<br>2. Using sterile technique, attach the appropriate sterile cannula seal to the cannula. **For the curved cannulae and 10 mm Accessory Cannula, ensure that the seal is visibly seated around the circumference of the cannula bowl. For the 5 mm Accessory Cannula, twist the seal until it clicks into place. For the 8.5 mm Endoscope Cannula, ensure that all four tabs on the seal are over the cannula lip.** |

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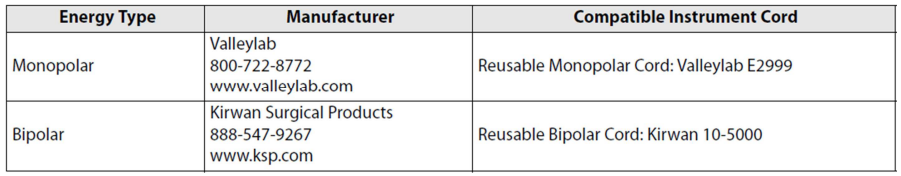
| Single-Site OUS Manual | Section 10.2 | The corresponding maximum ESU power settings to stay below the 3kV peak limit are as follows. | Added: The **approved ESUs, Monopolar Coag Modes and** corresponding maximum ESU power settings to stay below the 3kV peak limit are as follows. **Do not use an unlisted ESU or Monopolar Coag mode.** |

# Improper ESU Connections

| **Manual** | **Location** | **Original** | **Change** |
|---|---|---|---|
| *da Vinci* Si System Manual | Section 1.4 | First Bullet:<br>Place the dispersive electrode as close as possible to the operating field. | First Bullet:<br>**Ensure that** the dispersive electrode **is securely affixed to the patient, placed as close as possible to the operating field, and properly connected to the ESU** |
| Instruments and Accessories User Manual | Section 3.2 | N/A | Add Caution after Table 3-2:<br>**CAUTION: Connect the ESU to the EndoWrist instrument using the appropriate monopolar/bipolar instrument cord. Refer to the ESU's manual for indications and instructions in making this connection. Monopolar cords may only be connected to monopolar receptacles, and bipolar cords to bipolar receptacles.** |
| Instruments and Accessories User Manual | Section 3.2 | N/A | Added "Instrument Cord Connections" instructions and Table 3-2 Compatible Instrument Cords for Monopolar and Bipolar Energy:<br>  |
| Instruments and | Section 3.2 | N/A | Added : |

| Energy Type | Manufacturer | Compatible Instrument Cord |
|---|---|---|
| Monopolar | Valleylab<br>800-722-8772<br>www.valleylab.com | Reusable Monopolar Cord: Valleylab E2999 |
| Bipolar | Kirwan Surgical Products<br>888-547-9267<br>www.ksp.com | Reusable Bipolar Cord: Kirwan 10-5000 |

## Attachment C – Identification of Labeling Changes

<table>
<tr><td>Accessories User Manual</td><td></td><td></td><td>Image of the Megadyne generator in Figure 3.10 Instrument Cord Connections.</td></tr>
<tr><td>Instruments and Accessories User Manual</td><td>Section 3.3</td><td>N/A</td><td>Added Note:<br>Note: Ensure that the monopolar instrument cord is plugged into the monopolar receptacle on the ESU and that the bipolar instrument cord is plugged into the bipolar receptacle on the ESU.</td></tr>
<tr><td>Instruments and Accessories User Manual</td><td>Section 3.3</td><td>N/A</td><td>Added Note:<br>Note: The Covidien Force FX-C has multiple monopolar outputs. In this case, there are two receptacles on the front for the monopolar instrument cord and two outlets on the back for the energy activation cable. Ensure that the monopolar instrument cord is plugged into the receptacle corresponding to the outlet that the energy activation cable is plugged into.</td></tr>
<tr><td>Instruments and Accessories User Manual</td><td>Section 7.2</td><td>Step 2 in "Generator Settings":Connect the Gyrus ACMI generator to the plug connector on the PK Dissecting Forceps using the appropriate configuration as shown below:</td><td>Added to Step 2 in "Generator Settings":Connect the Gyrus ACMI generator to the plug connector on the PK Dissecting Forceps using the appropriate configuration as shown below:<br>Table 7-1 PK Instrument Cord Configuration<br><table><tr><th>Gyrus ACMI Generator Type</th><th>ISI PK Instrument Cord PN</th></tr><tr><td>G400 Generator[a]</td><td>400229</td></tr></table>a. Minimum recommended software level for Gyrus ACMI G400 is v1.08<br>Verify that the plug is fully inserted by confirming that the base is flush with the connector on the instrument housing.</td></tr>
</table>

## Attachment C – Identification of Labeling Changes

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| Instruments and Accessories User Manual | Section 3.3 | Step 3 in "Electrosurgical Unit (ESU) Preparation" section:<br>Connect the ESU to the EndoWrist instrument using the appropriate monopolar/bipolar instrument cord. Refer to the ESU's manual for indications and instructions in making this connection. For Gyrus ESUs, refer to Chapter 7 PK® Dissecting Forceps. | Added to Step 3 in "Electrosurgical Unit (ESU) Preparation" section:<br>Connect the ESU to the EndoWrist instrument using the appropriate monopolar/bipolar instrument cord**. Instrument energy cords are properly connected to the instruments when the connector completely covers the exposed pins.**Refer to the ESU's manual for indications and instructions in making this connection. For Gyrus ESUs, refer to Chapter 7 PK® Dissecting Forceps. |
| Instruments and Accessories User Manual | Section 3.1 | N/A | Added Warning:<br>**WARNING: The return electrode must be properly affixed to the patient before the use of electrocautery, to prevent patient or operator injury.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Added Note under Monopolar Cautery Settings section:<br><br>**Note: Refer to the Instruments and Accessories User Manual (PN 550675) for appropriate instrument cord connections and for proper setup instructions pertaining to use of the ERBE ICC 350, ERBE VIO 300D and Covidien Force Triad generators.** |
| Single-Site OUS Manual | Section 10.2 | N/A | Added Warning:<br>**WARNING: Patient dispersive electrode must be properly applied to the patient and plugged into the ESU prior to the use of electrocautery.** |

<table>
<tr><td>Single-Site OUS Manual</td><td>Section 10.2</td><td>N/A</td><td>Added: Table 10-3 Compatible Instrument Cords for Monopolar and Bipolar Energy<br><table><tr><th>Energy Type</th><th>Compatible Instrument Cord</th></tr><tr><td>Monopolar</td><td>Reusable Monopolar Cord: Valleylab E2999</td></tr><tr><td>Bipolar</td><td>Reusable Bipolar Cord: Kirwan 10-5000</td></tr></table></td></tr>
<tr><td>Single-Site OUS Manual</td><td>Section 10.2</td><td>Step 3 section:<br>a. Delete "monopolar" in first sentence.<br>b. Connect the ESU to the Single-Site instrument using the appropriate instrument cord. Refer to the ESU's manual for indications and instructions in making this connection.</td><td>Updated Step 3 section:<br>a. Delete "monopolar" in first sentence.<br>b. Connect the ESU to the Single-Site instrument using the appropriate instrument cord. Refer to the ESU's manual for indications and instructions in making this connection. Ensure that the monopolar instrument cord is plugged into the monopolar receptacle on the ESU and that the bipolar instrument cord is plugged into the bipolar receptacle on the ESU. Instrument energy cords are properly connected to the instruments when the connector completely covers the pins.</td></tr>
<tr><td colspan="4">Moving Instrument While Out of View</td></tr>
<tr><td>Manual</td><td>Location</td><td>Original</td><td>Change</td></tr>
<tr><td>da Vinci Si System Manual</td><td>Section 9.4</td><td>N/A</td><td>Added Warning:<br>WARNING: Use appropriate caution when inserting instruments into the patient by visualizing the instrument on the touchscreen as it is being inserted.</td></tr>
</table>

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| *da Vinci* Si System Manual | Section 9.4 | CAUTION: Removal of instruments during a procedure should be done very carefully and only with the knowledge of and full view of the Surgeon Console operator. | Updated Caution:CAUTION: Removal of instruments during a procedure should be done very carefully and only with the knowledge of and full view of the Surgeon Console operator. **Do not remove the instrument if it is not in view.** |
| Vessel Sealer User Manual | Section 2.3 | N/A | Added Warning:<br>**WARNING: Always insert and remove the instrument under visualization.** |
| *da Vinci* Si System Manual | Section 9.4 | Instrument Removal Steps:<br>1.Before instrument removal, the Surgeon Console operator should do the following:<br>a. Ensure the instrument tip is free and clear of any patient anatomy.<br>b. Straighten the instrument wrist.<br>c. Open the instrument jaws (instrument removal is difficult with jaws closed).<br>d. Clearly communicate to the Patient Cart operator which instrument to remove. Identify the name of the instrument or the number of the instrument arm (e.g., instrument arm 1, 2, 3).<br>2.Once the instrument is positioned for removal, the Patient Cart operator should squeeze the release levers on | Updated Instrument Removal Steps:<br><br>1.Before instrument removal, the Surgeon Console operator should do the following:<br>a. Ensure **that the instrument tip is in view and is free of** any patient anatomy.<br>b. Straighten the instrument wrist.<br>c. Clearly communicate to the **patient-side assistant** which instrument to remove. Identify the name of the instrument or the number of the instrument arm (e.g., instrument arm 1, 2, 3).<br>2.Once the instrument is positioned for removal, the **patient-side assistant** should squeeze the release levers on the sides of the instrument and pull the instrument out |

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|---|---|---|---|
| | | the sides of the instrument and pull the instrument out, then clear the sterile adapter. | |
| *da Vinci* Si System Manual | Section 9.4 | WARNING: The instrument may not be immediately visible when being moved from the cannula into the patient. Use appropriate caution when manually inserting instruments into the patient. | Updated Warning:<br>WARNING: The instrument may not be immediately visible when being moved from the cannula into the patient. **Move the endoscope to visualize the instrument and** use appropriate caution when inserting instruments into the patient. |

## Surgical Error Unrelated to System Use

| **Manual** | **Location** | **Original** | **Change** |
|---|---|---|---|
| *da Vinci* Si System Manual | Section 1.4 | Third bullet:<br>Do not deliberately or unintentionally energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view. | Third bullet:<br>Do not deliberately or unintentionally use one instrument to energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view. **This damage could occur at points near the tip or at the port site (cannula) of the energized instrument** |
| Instruments and Accessories User Manual | Section 19.2 | Step 4 in "Intraoperative Use" Section:<br>4.Create a skin incision using standard surgical procedure. Introduce the cannula and obturator assembly, applying continuous, controlled pressure on the obturator. | Added and updated Step 5 (formerly Step 4) in "Intraoperative Use":<br>Create a skin incision using standard surgical procedure. **Under vision,** introduce the cannula and obturator assembly, applying continuous, controlled pressure on the obturator. **Make sure that the obturator tip is pointing away from anatomic structures during insertion.** |

## Attachment C – Identification of Labeling Changes

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 2.1 | N/A | Added bullet:<br>**Do not deliberately or unintentionally use one instrument to energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site (cannula) of the energized instrument.** |
| Instruments and Accessories User Manual | Section 4.1 | N/A | Added bullet:<br>**Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.** |
| Instruments and Accessories User Manual | Section 19.2 | N/A | Added new Step 4 in "Intraoperative Use": **Before introducing the cannula, ensure that the patient is positioned to shift organs away from the port placement site and that an adequate level of insufflation has been achieved.** |
| Instruments and Accessories User Manual | Section 4.1 | Bullet:<br>Be aware of critical anatomy in contact with the instrument during energy activation: While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. | Added to bullet:<br>Be aware of critical anatomy in contact with the instrument during energy activation: While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. **The instrument should not be used as a retractor while applying energy.** |

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 5.1<br><br>Section 16.1 | N/A | Added under General Precautions and Warnings:<br><br>**• Do not apply energy when the instrument tip is not in contact with tissue: Energy should not be applied to an instrument when it is not in direct contact with tissue (referred to as "air-firing"). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.**<br><br>**• Be aware of critical anatomy in contact with the instrument during energy activation: While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.**<br><br>**• Survey the surgical field: During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas "below" or "behind" the cannula and endoscope that are normally outside the field of view.**<br><br>**• Consider patient condition: Before using monopolar cautery in a procedure, consider factors that may make a patient's anatomy and tissue more susceptible to injury from the application of cautery (for example, patients that have received radiation therapy prior to surgery).**<br><br>**Additional changes for section 5.1 only:**<br><br>**• The Instrument must always be used in conjunction with the appropriately sized Intuitive Surgical 8 mm metal cannula.**<br><br>**• The Instrument should never be used with an Intuitive Surgical 8 mm metal cannula inserted through a plastic cannula.** |

| | | | |
|---|---|---|---|
| Instruments and Accessories User Manual | Section 4.1<br>Section 5.1<br>Section 16.1 | N/A | Added Warning:<br>**WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the end effectors or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.** |
| Instruments and Accessories User Manual | Section 4.1 | N/A | Added under General Precautions and Warnings:<br>**Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.** |
| Instruments and Accessories User Manual | Section 5.2<br>Section 16.1 | N/A | Added Warning:<br>**WARNING: Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.** |
| Instruments and Accessories User Manual | Section 19.1 | Bullet in "CAUTION: To minimize the risks associated with port placement, ensure the following:"<br>When possible, visualization of the entire insertion of the cannula using the endoscope is preferred. | Removed "When possible" from bullet in "CAUTION: To minimize the risks associated with port placement, ensure the following:"<br>Visualization of the entire insertion of the cannula using an endoscope is preferred. |

## Attachment C – Identification of Labeling Changes

| | | | |
|---|---|---|---|
| Single-Site OUS Manual | Section 7 | N/A | Added "A. **Ensure that the patient is positioned to shift organs away from the port placement site and that an adequate level of insufflation has been achieved, before introducing the cannulae."** under "For patient safety during insertion of Single-Site curved cannulae…". |
| Single-Site OUS Manual | Section 15.2 | N/A | Added Caution:<br>**CAUTION: Ensure that the remote centers of all cannulae are within the boundaries of the Single-Site port. Failure to position the remote centers appropriately may generate excessive forces on the patient body wall, damage the port or cannulae, or result in loss of insufflation.** |
| Single-Site OUS Manual | Section 11.1 | N/A | Added Warning:<br>**WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the end effectors or injure tissue inside or outside the field of view. This damage could occur at points near the instrument tip or cannula.** |
| Single-Site OUS Manual | Section 11.1 | N/A | Added Warning:<br>**WARNING: Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.** |
| Single-Site OUS Manual | Section 12.1 | Bullet:<br>Avoid contact with a monopolar instrument that may result in damage | Updated bullet:<br>Avoid contact with a**n active** monopolar instrument**. This** may result in **harm to the patient or** damage to the ESU. |

| | | | |
|---|---|---|---|
| | | to the ESU. | |
| Vessel Sealer User Manual | Section 1.5 | N/A | Added Warning:<br>**WARNING: Exercise caution when working with monopolar instruments close to the Vessel Sealer. Unintended energy may be delivered from the active monopolar instrument to the Vessel Sealer. This could result in burns to tissue in contact with any of the Vessel Sealer's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the Vessel Sealer.** |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment D – Affected Manuals, IFU's, QRG's and IRK by Language and Country

| Language | Country | IS3000 User Manual | Single-Site User Manual** | Stapler 45 I-A User Manual Addendum | I&A User Manual | Vessel Sealer User Manual | Vessel Sealer QRG | Grip Release QRG | Grip Release Addendum IS1200 | ESU Setting QRG | Core Connection QRG | NRL QRG | IS2000 User Manual | Trouble-shooting Flow Charts | IRK with Vessel Sealer |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| US English | United States | 550650-07_A | 551184-06_E | 550986-06_D | 550675-06_G | 551027-07_F | 551182-05_D | 551979-05 | 551980-02 | 551992-02 | 551993-02 | 551997-01 | 550516-06_C | 550866-03_B | 381199-01 |
| EU English | Canada*<br>Great Britain<br>Ireland<br>Israel<br>Qatar<br>Lebanon<br>Pakistan<br>Kuwait<br>South Africa<br>India<br>Singapore<br>Thailand<br>Malaysia<br>Philippines<br>Indonesia<br>Australia<br>New Zealand<br>Saudi Arabia<br>Egypt*<br>Iceland<br>Hong Kong | 550650-07_A | 550965-09_A | NA | 550675-06_G | 551027-07_F | 551182-05_D | 551979-05 | 551980-02 | 551992-02 | 551993-02 | 551997-01 | 550516-06_C | 550866-03_B | 381199-01 |
| Bulgarian | Bulgaria | 550651-06_A | 551056-04_A | NA | 550676-05_A | 551271-06_A | 552600-01_A | 552632-01 | NA | 552685-01 | 552711-01 | 552737-01 | 550537-02_A | 551090-02_A | 381256-01 |
| Simplified Chinese | China<br>Hong Kong | 550667-06_A | 551057-03_A | NA | 550692-05_A | 551272-06_A | 552601-01_A | 552633-01 | 552660-01 | 552686-01 | 552712-01 | 552738-01 | 550524-02_A | 551091-02_A | 381257-01 |
| Traditional Chinese | Taiwan | 551118-05_A | 551383-03_A | NA | 551125-04_A | 551273-06_A | 552602-01_A | 552634-01 | 552661-01 | 552687-01 | 552713-01 | 552739-01 | 551528-02_A | 552763-01_A | 381258-01 |
| Czech | Czech Republic | 550652-06_A | 551059-04_A | NA | 550677-05_A | 551275-06_A | 552604-01_A | 552636-01 | 552663-01 | 552689-01 | 552715-01 | 552741-01 | 550525-02_A | 551093-02_A | 381260-01 |
| Danish | Denmark | 550653-06_A | 551060-05_A | NA | 550678-05_A | 551276-06_A | 552605-01_A | 552637-01 | 552664-01 | 552690-01 | 552716-01 | 552742-01 | 550518-04_A | 551094-02_A | 381261-01 |
| Dutch | Belgium<br>Netherlands | 550654-06_A | 551061-05_A | NA | 550679-05_A | 551277-06_A | 552606-01_A | 552638-01 | 552665-01 | 552691-01 | 552717-01 | 552743-01 | 550517-04_A | 551095-02_A | 381262-01 |
| Finnish | Finland | 550655-06_A | 551062-04_A | NA | 550680-05_A | 551278-06_A | 552607-01_A | 552639-01 | NA | 552692-01 | 552718-01 | 552744-01 | 550526-02_A | 551096-02_A | 381263-01 |
| French | France<br>Belgium<br>Switzerland<br>Monaco<br>Guadeloupe<br>Luxembourg | 550656-06_A | 551063-05_A | NA | 550681-05_A | 551279-06_A | 552608-01_A | 552640-01 | 552667-01 | 552693-01 | 552719-01 | 552745-01 | 550523-04_A | 551097-02_A | 381264-01 |
| French (Canada) | Canada* | 550656-06_A | NA | NA | 550681-05_A | NA | NA | 552640-01 | 552667-01 | 552693-01 | 552719-01 | 552745-01 | 550523-04_A | 551097-02_A | 381264-01 |
| German | Germany<br>Belgium<br>Switzerland<br>Austria<br>Luxembourg | 550657-06_A | 551064-05_A | NA | 550682-05_A | 551280-06_A | 552609-01_A | 552641-01 | 552668-01 | 552694-01 | 552720-01 | 552746-01 | 550522-04_A | 551098-02_A | 381265-01 |
| Greek | Greece<br>Cyprus | 550658-06_A | 551065-05_A | NA | 550683-05_A | 551281-06_A | 552610-01_A | 552642-01 | 552669-01 | 552695-01 | 552721-01 | 552747-01 | 550527-03_A | 551099-02_A | 381266-01 |
| Italian | Switzerland<br>Italy | 550659-06_A | 551067-05_A | NA | 550684-05_A | 551283-06_A | 552612-01_A | 552644-01 | 552671-01 | 552697-01 | 552723-01 | 552749-01 | 550520-04_A | 551101-02_A | 381268-01 |

# Urgent Medical Device Correction – 2955842-05212014-002-C

## Attachment D – Affected Manuals, IFU's, QRG's and IRK by Language and Country

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Japanese | Japan | 550660-05_A | 551068-03_A | NA | 550972-04_A | 551284-06_A | 551989-01_A | 552645-01 | NA | 552900-01 | 552901-01 | 552902-01 | 550970-03_A | 551102-02_A | 381269-01 |
| Korean | South Korea | 550661-06_A | 551069-03_A | NA | 550686-05_A | 551285-06_A | 552613-01_A | 552646-01 | NA | 552698-01 | 552724-01 | 552750-01 | 550529-03_A | 551103-02_A | 381270-01 |
| Norwegian | Norway | 550663-06_A | 551071-04_A | NA | 550688-05_A | 551287-06_A | 552615-01_A | 552648-01 | 552674-01 | 552700-01 | 552726-01 | 552752-01 | 550531-03_A | 551105-02_A | 381272-01 |
| Polish | Poland | 550671-05_A | 551072-04_A | NA | 550580-04_A | 551288-06_A | 552616-01_A | 552649-01 | NA | 552701-01 | 552727-01 | 552753-01 | NA | 551106-02_A | 381273-01 |
| Portuguese | Portugal<br>Brazil | 550664-06_A | 551073-04_A | NA | 550689-05_A | 551289-06_A | 552617-01_A | 552650-01 | NA | 552702-01 | 552728-01 | 552754-01 | 550535-03_A | 551107-02_A | 381274-01 |
| Romanian | Romania | 550665-06_A | 551074-04_A | NA | 550690-05_A | 551290-06_A | 552618-01_A | 552651-01 | NA | 552703-01 | 552729-01 | 552755-01 | 550532-02_A | 551108-02_A | 381275-01 |
| Russian | Russia | 550666-05_A | 551075-04_A | NA | 550691-04_A | NA | NA | 552652-01 | NA | 552704-01 | 552730-01 | 552756-01 | 550533-03_A | 551109-02_A | 381253-01 |
| Slovakian | Slovak Republic | 551391-03_A | 551394-03_A | NA | 551392-03_A | 551399-04_A | 552622-01_A | 552654-01 | NA | 552706-01 | 552732-01 | 552758-01 | NA | 551526-02_A | 381277-01 |
| Slovenian | Slovenia | 550428-05_A | 551076-04_A | NA | 550637-04_A | 551293-06_A | 552621-01_A | 552655-01 | NA | 552707-01 | 552733-01 | 552759-01 | 550564-02_A | 551110-02_A | 381278-01 |
| Spanish | Spain<br>Mexico<br>Argentina<br>Chile<br>Venezuela<br>Colombia<br>Uruguay<br>Dominican Republic<br>Puerto Rico<br>Panama | 550668-06_A | 551077-04_A | NA | 550693-05_A | 551294-06_A | 552623-01_A | 552656-01 | 552682-01 | 552708-01 | 552734-01 | 552760-01 | 550521-04_A | 551111-02_A | 381279-01 |
| Swedish | Sweden<br>Finland | 550669-06_A | 551078-04_A | NA | 550694-05_A | 551295-06_A | 552624-01_A | 552657-01 | 552683-01 | 552709-01 | 552735-01 | 552761-01 | 550519-04_A | 551112-02_A | 381280-01 |
| Turkish | Turkey | 550670-06_A | 551079-05_A | NA | 550695-05_A | 551296-06_A | 552625-01_A | 552658-01 | 552684-01 | 552710-01 | 552736-01 | 552762-01 | 550534-02_A | 551113-02_A | 381281-01 |

*Vessel Sealer labeling not available in this country.

**Includes separate documentation for Single-Site reprocessing. Documentation includes updated reprocessing instructions in anticipation of new product introductions.